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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	**Application No.** 10/679,116	**Applicant(s)** TROUVE ET AL.
	Examiner Carlic K. Huynh	**Art Unit** 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *26-29 and 49-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 30-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *19 May 2004*.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-52 are pending in the application, with claims 26-29 and 49-52 having been withdrawn from consideration, in response to the restriction requirement submitted on October 20, 2006. Accordingly, claims 1-25 and 30-48 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election with traverse of Group I, namely claims 1-25 and 30-48, in the reply filed on December 20, 2006 is acknowledged. The traversal is on the ground(s) that the search for the product of Group I would uncover the process of Group II.. This is not found persuasive because many products can be used with the process of Group II and thus the search for the products of Group I will not necessarily yield the process of Group II. Furthermore, if the product claims of Group I are found allowable, then the process claims of Group II will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, as per *In re Ochiai.*

Claims 26-29 and 49-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on December 20, 2006.

The restriction requirement is still deemed proper and is therefore made FINAL.

3. Applicant's election with traverse of the species of (1) white mineral oils (fatty phase); (2) calcium hydroxide (multivalent cation salt); (3) sodium alginate (anionic polymer); and (4) sorbitan monooleate (nonionic surfactant), in the reply filed on December 20, 2006 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Examiner hereby withdraws the election of species requirement of (2) calcium hydroxide for the multivalent cation salt and (3) sodium alginate for the anionic polymer.

The election of species requirement of (1) white mineral oils for the fatty phase and (4) sorbitan monooleate for the nonionic surfactant is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on May 19, 2004 is acknowledged.

Claim Objections

4. Claims 45-46 objected to because of the following informalities: claim 45 is improperly dependent on claim 45; and claim 45 is improperly dependent on claim 45. It is noted that claim 44 is directed to esters of sugars and to ethers of sugars. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-25 and 31-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brancq et al. (U.S. Patent 5,422,109) in view of Balassa (U.S. Patent 3,780,195), Shechmeister et al. (U.S. Patent 3,925,544), and Van Slyke (U.S. Patent 5,780,407).

Brancq et al. teach an injectable emulsion comprising of a mineral oil and a nonionic surfactant, a mannitol ester (column 1, lines 34-35). The mineral oil is 42.5% by weight of the composition (column 2, example 1). The HLB (hydrophile-lipophile balance) of the surfactant and oil is between 2 and 9 (column 5, lines 61-64).

Brancq et al. teach neither the organometallic gel, which comprise an anionic polymer and a multivalent metal cation, nor sorbitan monooleate as the nonionic surfactant.

Shechmeister et al. teach polyvalent vaccines that contain the organometallic gel components, which are 4 percent weight/volume sodium alginate as the anionic polymer and 0.67 percent by weight calcium gluconate as the multivalent metal cation (column 3, lines 48-51). It is noted that concentration of metal cations [C], expressed in mol/liter, for calcium gluconate is calculated to be 1.56×10^{-2} mol/liter. Additionally, the ratio of the concentration of anionic polymer [P]/[C] is calculated to be 5.97. Furthermore, the concentration of sodium alginate and calcium gluconate is sufficient to precipitate as an insoluble alginate gel before injection (column 3, lines 44-45).

Balassa teaches shell compositions containing starch ethers and esters of either sorbitan or mannitol, such as sorbitan monooleate and mannitol monooleate (column 3, lines 39 and 44-45).

Van Slyke teaches compositions comprising a surfactant and a diluent oil for oil-based drilling fluids (abstract). The composition contains 64.7% white mineral oil as the diluent oil and 8.1% sorbitan monooleate as the surfactant (examples 55-59, Table B).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the mineral oil composition of Brancq et al. to contain an organometallic gel made up of an anionic polymer and a multivalent metal cation because the compounds of Shechmeister et al., are anionic polymers and multivalent metal cations and according to Shechmeister et al., mineral oil compositions contain anionic polymers and multivalent metal cations.

The motivation to combine the compounds of Brancq et al. to the compounds of Shechmeister et al. is that the compounds of Shechmeister et al. are mineral oil compositions that contain anionic polymers and multivalent metal cations.

To a person of skill in the art at the time of the invention, it would have been obvious to employ the mineral oil-nonionic surfactant composition of Brancq et al. to contain a specific nonionic surfactant such as sorbitan monooleate because the compounds of Balassa and Van Slyke are nonionic surfactants and according to Balassa, mannitol monooleate and sorbitan monooleate are art equivalent nonionic surfactants.

The motivation to combine the compounds of Brancq et al. to the compounds of Balassa and Van Slyke is that the compounds of Balassa are the art equivalent nonionic surfactants mannitol monooleate and sorbitan monooleate.

Regarding the fatty phase in instant claims 1, 3-9, 21, 32-35, these claims have been read on the elected species of white mineral oils.

Regarding the nonionic surfactant in instant claims 22-25 and 44-48, these claims have been read on the elected species of sorbitan monooleate.

Regarding HLB in instant claim 47, Brancq et al. teach HLB of the surfactant and oil is between 2 and 9, which meets the limitations of the instant claim. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the aqueous solution temperature provided in a composition, according to the guidance set forth in Nyberg et al., to provide a composition having the desired aqueous solution temperature. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding [C] in instant claim 39, Shechmeister et al. teach [C] is 1.56×10^{-2} mol/liter, which meets the limitations of the instant claim. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the aqueous solution temperature provided in a composition, according to the guidance set forth in Nyberg et al., to provide a composition having the desired aqueous solution temperature. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

6. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brancq et al. (U.S. Patent 5,422,109) in view of Shechmeister et al. (U.S. Patent 3,925,544) and Ganne et al. (FR 2754715).

Brancq et al. teach an emulsion comprising of a mineral oil (column 1, lines 34-35).

Brancq et al. teach neither the organometallic gel, which comprise an anionic polymer and a multivalent metal cation, nor at least one antigen or at least one generator in vivo of a compound comprising an amino acid sequence.

Shechmeister et al. teach polyvalent vaccines containing the organometallic gel components, which are sodium alginate as the anionic polymer and calcium gluconate as the multivalent metal cation (column 3, lines 48-51).

Ganne et al. teach a composition containing at least one antigen or at least one in vivo generator of a compound comprising an amino acid sequence (abstract).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the mineral oil of Brancq et al. to contain an organometallic gel and an antigen because the compounds of Shechmeister et al., are anionic polymers and multivalent metal cations, the components of the organometallic gel, and the compounds of Ganne et al. are antigens and according to Shechmeister et al., mineral oil compositions contain anionic polymers and multivalent metal cations and according to Ganne et al., mineral oil compositions contain antigens.

The motivation to combine the compounds of Brancq et al. to the compounds of Shechmeister et al., and Ganne et al. is that the compounds of Shechmeister et al. are mineral oil compositions containing anionic polymers and multivalent metal cations, and the compounds of Ganne et al. are antigens.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1 and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of copending Application Aucouturier et al. (U.S. Serial No. 09/698,121). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 19 of the Aucouturier et al. application is directed at a method of providing an adjuvant effect to a vaccine comprising an antigen with a surfactant, which is the same antigen and surfactant used in a pharmaceutical composition in the

instant claims 1 and 30. Thus the antigen and surfactant composition is not patentably distinct between the Aucouturier et al. application and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

8. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of Trouve (6,103,770) claim 1 of Trouve (6,221,919). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 22 of the Trouve patent and claim 1 of the Trouve patent are directed at a method of preparing a pharmaceutical product in the form of a stable emulsion comprising an ethoxylated fatty ester, which is the same fatty acid ester used in a pharmaceutical composition in the instant claim 1. Thus the fatty acid ester composition is not patentably distinct between the Trouve patents and the instant application.

9. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10 of copending Application Trouve (U.S. 2006/010110) in view of Brancq et al. (U.S. Patent 5,422,109), Balassa (U.S. Patent 3,780,195), Shechmeister et al. (U.S. Patent 3,925,544), and Van Slyke (U.S. Patent 5,780,407) as applied to claims 1-25 and 31-48 above.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

10. Claims 1 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, and 10 of Brancq et al. (5,422,109) and claims 1 and 6 of Brancq et al. (5,424,067) in view of Brancq et al. (U.S. Patent 5,422,109), Balassa

(U.S. Patent 3,780,195), Shechmeister et al. (U.S. Patent 3,925,544), and Van Slyke (U.S. Patent 5,780,407) as applied to claims 1-25 and 31-48 above and in further view of Ganne et al. (FR 2754715) as applied to claim 30 above.

11. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of Trouve (6,103,770) and claims 4, 6-7, 9-10, 12-13, 16-17, and 19 of Trouve (6,221,919) in view of Brancq et al. (U.S. Patent 5,422,109), Balassa (U.S. Patent 3,780,195), Shechmeister et al. (U.S. Patent 3,925,544), and Van Slyke (U.S. Patent 5,780,407) as applied to claims 1-25 and 31-48 above.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

S. Wang

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